

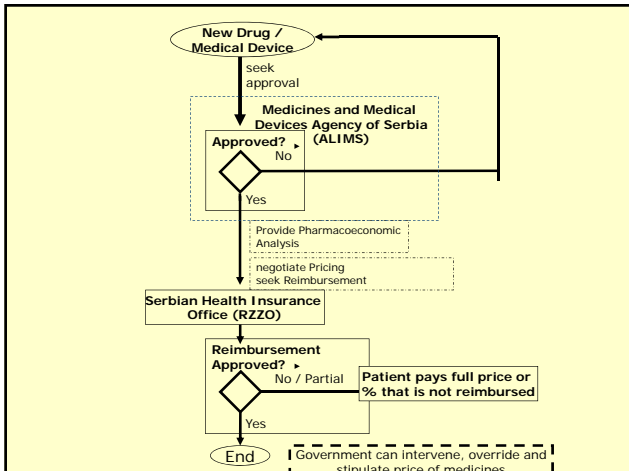
**HTA DEVELOPMENTS IN THE CENTRAL AND EASTERN EUROPEAN (CEE) REGION: LOCK, STOCK & BARREL IN CHALLENGING TIMES**  
**REPUBLIC OF SERBIA**



Republic of Serbia

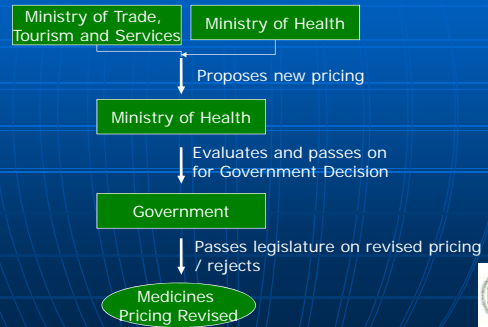


What is a process flow for a new drug / medical device entering Serbian marketplace?




**Current State of Affairs**

**Government can intervene, override and stipulate price of medicines**



## Current State of Affairs



**Con's Pricing**

- lack of innovation stimulation (branded product cannot exceed 20% of the generic price);


**Reimbursement**

- lack of transparency and Evidence Based Medicine use;
- insufficient resources to handle Health Technology Assessment.


**Pro's Assessment**

- HTA is required!

Evidence Based Medicine and Health Technology Assessment are acknowledged as very important future factors. Health Economic training is established within academic institutions. **Guidelines set within reimbursement process (May 2011).**



## Current State of Affairs - Now




The market is expected to reach 920 million euros (\$1.21 billion) in 2011 in wholesale prices, or around 1.1 billion euros in retail prices, according to Miodir Nikolic, the head of the Serbian Chamber of Commerce's group of drug wholesalers, who cover 85 percent of the market. (Jan 2011)

The NIF owes 9.5 billion dinars (€95 mil/\$120 mil) to wholesalers who then owe about as much to manufacturers, he said. Growth will continue even with a "chronic" lack of liquidity in the Serbian health-care system as bills for drugs delivered are paid with an average delay of 90 days to 120 days

Serbian NIF (RZZO) signed agreement to receive 10% discount on all drugs (both generic and brand) reimbursed (on a positive list) from Pharma (estimated 4-5 mil euro) in 2011. - Feb 28, 2011

These savings will be used to improve patient care & introduce new innovative therapies to a positive list. Most likely, savings will be applied towards branded Oncology products, branded antibiotics and other products.



## Current State of Affairs - Now



**Serbian NIF (RZZO) draft price regulation (June 2011)**

Revisions to the current price regulations include the following:  
Price for brand product is to be no more than 20% of the price of generic.


**New positive list revised and accepted. Announced beginning of July 2011. It is continuously updated.**

New regulations will reflect on the criteria for placing and removing a product from the positive list. New Regulations will take into account necessity for the new therapy, pharmaco-economic indicators of justification for a new therapy application, as well as the wholesale price of a new therapy.

**Required: PharmacoEconomic analysis**  
(explained in article 20, point 14 )




## Current State of Affairs - Now

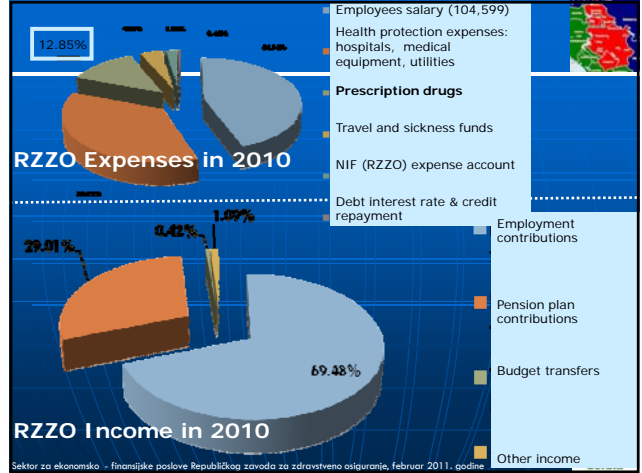
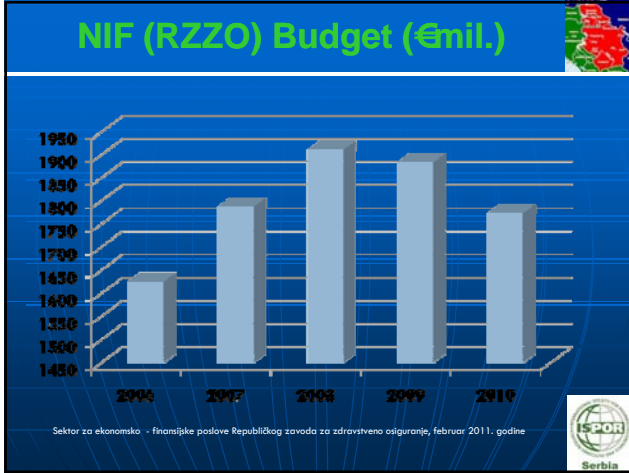


**Required: PharmacoEconomic analysis (article 20, point 14 )**

**Pharmacoeconomic parameters that confirm economic justification of usage of this medicine, expenses – benefits (effectiveness) in Serbian language, that contain minimum:**

- 1) **wholesale price of this medicine – daily drug dose (DDD);**
- 2) **therapy expenditure per insured person, for the appropriate length of treatment (number of days), by therapy cycle or on monthly level;**
- 3) **annual expenditure on therapy (for chronic diseases);**
- 4) **Comparator relation of expenses and effects between innovative or original medicine for which you are submitting Request & medicines for the same indication, in case that there are medicines on the existing (read:Positive) list.** Comparative ratio should be implemented using a suitable modeling technique (decision tree, markov model and other similar models), adjusted to current situation in the Republic of Serbia in terms of expenditure and/or effects of therapy;
- 5) **estimate number of insured persons that would be receiving the medicine, with calculated financial effect on total expenditure on medicines of National Insurance Fund (read: RZZO), on an annual level;**
- 6) **Tabular representation of the medicine presence on positive lists in EU countries and other countries.**





### Health Technology Assessment (HTA)

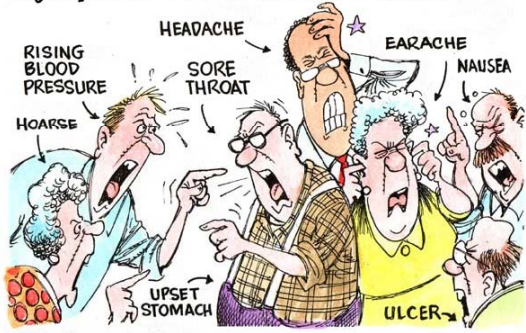
#### Health Technology and Decision making

“To be useful to decision makers, HTA must be tailored to the decision nodes of the health-care system and the needs and interests of decision makers at each of these nodes.”

The OECD Health Project. Health technology and Decision Making. Paris, France: OECD, 2005.

THANK YOU!

### Symptoms of the Healthcare Debate...



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